Ammonia and Ammonium Sulfate
Interim Registration Review Decision
Case Numbers 7440 & 5073

December 2018

Approved by: _____

Anita Pease
Acting Director
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Ammonia and Ammonium Sulfate
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Table of Contents

I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for Ammonia (PC Code 005601, Case Number 7440) and Ammonium Sulfate (PC Code 005302, Case 5073) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on ammonia and ammonium sulfate can be found in the Agency's public docket (EPA-HQ-OPP-2012-0684) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the Agency based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The Agency is issuing an Interim Decision for ammonia and ammonium sulfate so that it can move forward with aspects of the registration review that are complete. EPA determined that no pollinator exposure and effects data are necessary to make a final registration review decision for ammonia and ammonium sulfate. The Agency has evaluated risks to listed species. The Agency is making a "no effects" finding for listed species and designated critical habitat. The Agency will complete endocrine screening for ammonia and ammonium sulfate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), before completing registration review.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of any public comments received on the preliminary risk assessment and the Agency's responses; *Usage Information*, which describes how and why ammonia and ammonium sulfate are used; *Scientific Assessment*, which summarizes the Agency's risk assessments; the *Interim Registration Review Decision*, which describes the regulatory rationale for the Agency's interim registration review decision; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Ammonia and Ammonium Sulfate Registration Review

Pursuant to 40 CFR section 155.50, the Agency formally initiated registration review for ammonia and ammonium sulfate (PC Codes 005601 & 005302). The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of ammonia and ammonium sulfate:

- September 26, 2012 - The Ammonia and Ammonium Sulfate Preliminary Work Plan (PWP) was published to docket EPA-HQ-OPP-2012-0684 for a 60-day public comment. The public comment period closed November 26, 2012.

- February 20, 2013 - The Final Work Plan (FWP) for Ammonia and Ammonium Sulfate was published to docket EPA-HQ-OPP-2012-0684. During the PWP 60-day comment period, two comments were received from the public. The comments did not change the data needs, planned risk assessments, or the timeline for the registration review case; thus, the FWP did not modify the PWP.

- December 22, 2016 - The Amended Final Work Plan was completed and published to docket EPA-HQ-OPP-2012-0684. The amended FWP removed the previously anticipated 835.6200 aquatic field dissipation data requirement. All other elements of the Agency's Ammonia and Ammonium Sulfate FWP remained unchanged.

- December 29, 2016 - A Generic Data Call-In (GDCI) for ammonia and ammonium sulfate was issued for data needed to conduct the registration review risk assessments. All data have been waived and the GDCI is satisfied.

- February 27, 2018 - The Preliminary Risk Assessment for Ammonia and Ammonium Sulfate was published to docket EPA-HQ-OPP-2012-0684 for a 60-day public comment period. Several comments were received. The comments did not change the risk assessments or registration review timeline.

- June 25, 2018 - The Proposed Interim Decision was published to the docket EPA-HQ-OPP-2012-0684 for a 60-day public comment period. One comment was received, and the comment did not change the risk assessments or registration review timeline.

B. Public comments on the Proposed Interim Decision

During the 60-day public comment period on the Ammonia and Ammonium Sulfate Proposed Interim Decision, which opened June 25, 2018 and closed August 25, 2018, the Agency received one comment from the California Specialty Crops Council. The comment in its entirety can be found on the current docket for ammonia and ammonium sulfate (EPA-HQ-OPP-2012-0684). The comment was concerning insect pesticide resistance threatening crop yields and the need to rotate pesticides with differing modes of action. The comment does not specifically address risk from ammonia or ammonium sulfate uses or request any revision to the risk assessment or the registered use sites. The comment is associated with the non-pesticidal use of ammonia in

agricultural fields. Currently there are no registered uses of ammonia or ammonium sulfate in agricultural fields for the control of insects.

Agency Response: The Agency thanks the submitter for the comments. The comment did not affect the Agency's conclusions with respect to risk and did not alter the risk projections for ammonia and ammonium sulfate.

II. Usage Information

There are currently six registered pesticide products containing ammonia and ammonium sulfate. Four products incorrectly list ammonia (total) as the active ingredient when they contain ammonium sulfate (PC 005302) as the active ingredient. Two products are correctly listed as containing ammonium sulfate as the active ingredient. Therefore, the Agency assessed exposure and risk to the products in these cases as ammonium sulfate. The products are liquid soluble concentrates and contain 20% to 40% ammonium sulfate. As noted in the table in Appendix A, the Agency requires label amendments to correct the active ingredient listing.

Products containing ammonia and ammonium sulfate are registered for use to control algae, bacteria, fungi and mollusks in industrial systems (paper mills, recirculating cooling water systems, evaporative condensers, brewery and food pasteurizers, industrial fresh water systems, air washers, seawater desalination and reverse osmosis systems and paint spray booth sumps), non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems, and oil and gas systems. Ammonia and ammonium sulfate products are also registered for use to control algae, bacteria, fungi and mollusks in influent water systems (freshwater and seawater).

Products containing ammonia and ammonium sulfate are used in conjunction with sodium hypochlorite in a closed metered chemical feed system to produce monochloramine. The treatment can be administered using the slug, intermediate or continuous feed methods. The specified dose is 1 to 10 ppm available chlorine for both initial and subsequent treatments. Per the labels, prior to effluent release, the chloramine must be neutralized with sodium metabisulfite until chloramine is no longer detected. This neutralization results in the formation of ammonium and chloride ions, which are not of environmental or human health concern. Likewise, in aqueous media, ammonium sulfate dissociates into ammonium and sulfate ions, and under the heat of the paper finishing process, the chemical species likely to remain are ammonium ion, sulfate ion, nitrate ion, and chloride ion, for which there are no dietary concerns. Due to low potential for exposure and lack of toxicity from degradation products after ammonium sulfate use, a qualitative human health and environmental risk assessment was performed.

III. Scientific Assessment

A. Human Health Assessment

The most recent human health risk assessment for ammonium sulfate (D442473)[1] was completed in 2017 and nothing has changed since that assessment, therefore a qualitative assessment was done. The qualitative assessment did not include a quantitative human health risk assessment, based on the low potential for exposure and lack of toxicity in the database. The residues remaining in the finished paper have no dietary toxicity concerns. Even for products registered with ammonia as the active ingredient, the true active ingredient is believed to be ammonium sulfate; therefore, the exposure and risk assessment was conducted for ammonium sulfate only. For further information, please see, "Registration Review Preliminary Risk Assessment for Ammonia and Ammonium Sulfate" located in docket EPA-HQ-OPP-2012-0684 at www.regulations.gov.

1. Risk Summary and Characterization

The Agency has determined that risks to human health from the use of ammonia and ammonium sulfate are minimal based on no evidence of adverse effects and lack of exposure.

2. Human Incidents

No ammonia and ammonium sulfate related incidents have been reported in the Agency's Incident Data System (IDS) for the period from 1992 to September 13, 2017. IDS contain reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

3. Dietary Exposure/Tolerances

Since there are no food uses of ammonia and ammonium sulfate as an active ingredient, residues of ammonium sulfate are exempted from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408, when used as a solid diluent or carrier in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.910), without limit. Under the FFDCA Section 409, ammonium sulfate is listed by Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) when used as a direct food additive (21 CFR 184.1143).

Ammonia and ammonium sulfate produce no residues of potential toxicological concern that are expected to survive the paper manufacturing processes. Any chloramine not consumed in the water system is expected to degrade during the paper drying process. The remaining residues have no dietary toxicity concerns.

Further, very low levels of monochloramine may potentially be discharged from industrial water systems or paper mills; however, due to its rapid hydrolysis and biodegradation, it is not

[1] D442473. U.S. EPA. August 28, 2017. Qualitative Risk Assessment for New Ammonium Sulfate Product: Biosperse CX400.

expected to be stable in surface water. Therefore, no drinking water risks are expected from the registered uses of ammonia and ammonium sulfate.[2]

4. Food and Drinking Water

A dietary (food and drinking water) exposure assessment is not currently required for ammonia and ammonium sulfate. The FIFRA registered uses of ammonia and ammonium sulfate are not expected to result in direct or indirect dietary (food) exposure. The use of ammonia and ammonium sulfate products are not expected to pose a hazard to groundwater or surface waters; therefore, a drinking water assessment is not currently required.[3]

5. Occupational and Residential Exposures

No residential exposure scenarios are associated with use of ammonium sulfate. Therefore, there is no need to estimate residential risks.

The labels for the ammonia and ammonium sulfate products require the mixing of the product with sodium hypochlorite within an onsite feeder/delivery system which is a closed system. The ammonium sulfate is transferred from the shipping container to the feeder/delivery system via a closed loading system and therefore worker exposure to ammonium sulfate is not anticipated to be significant.[4]

6. Aggregate Risks

An aggregate exposure risk assessment was not conducted for this chemical because of a lack of dietary and residential exposure.[4]

7. Cumulative Risks

Unlike other pesticides for which the Agency has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding as to ammonia and ammonium sulfate and any other substances and ammonia and ammonium sulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, the Agency has not assumed that ammonia and ammonium sulfate have a common mechanism of toxicity with other substances.[4]

8. Human Health Data Needs

The Agency does not anticipate any further human health data needs for the ammonia and ammonium sulfate registration review.[4]

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[2] Registration Review of ammonium sulfate human health scoping document (D404903, D401474) conducted in 2012 and available in docket EPA-HQ-OPP-2012-0684 at www.regulations.gov.
[3] Ammonia and Ammonium Sulfate: Human Health Registration Review Scoping Document (D404903, D401474) conducted in 2012 and available in docket EPA-HQ-OPP-2012-0684 at www.regulations.gov.
[4] Ammonia and Ammonium Sulfate Draft Risk Assessment EPA-HQ-OPP-2012-0684 at www.regulations.gov.

B. Environmental Assessment

The Agency does not anticipate any significant risks to non-listed or listed species (aquatic, and terrestrial, including pollinators). Label restrictions prevent exposure into surface water, and the environmental fate data indicate strong sorption to sediment. Ammonia and ammonium sulfate have no outdoor registered uses. Due to lack of exposure, ammonia and ammonium sulfate pose no ecological risk to aquatic organisms or pollinators.

The only compounds of potential ecotoxicity concern from treated paper mill and industrial water systems are traces of chloramine and hypochlorous acid. These compounds are neutralized before being released into the environment. Therefore, only very low levels of these compounds would be discharged, and these would rapidly dissipate and biodegrade. Therefore, risks to non-target organisms are not expected from the ammonia and ammonium sulfate uses.

Based on ammonia and ammonium sulfate's physical and environmental fate properties, ammonia and ammonium sulfate are highly volatile substances and can easily transfer into the atmosphere; however, its half-life in air is short, and it is likely to rapidly degrade. Ammonia and ammonium sulfate are highly water soluble, and under aerobic conditions they undergo ready biodegradation. The available ecotoxicity data categorize ammonia and ammonium sulfate as being practically non-toxic to birds and aquatic organisms. For more information, please refer to "Ammonia and Ammonium Sulfate: Product Chemistry/Environmental Chemistry and Eco-Effects Scoping Document," located in docket EPA-HQ-OPP-2012-0684 at www.regulations.gov.

1. Environmental Fate and Exposures

When mixed with sodium hypochlorite in water systems, ammonia and ammonium sulfate turn into monochloramine (chloramine). All labels state "if chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until chloramine is no longer detected." Some labels also state that "residual levels of monochloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment." The neutralization results in the formation of ammonium and chloride ions, which are not of environmental concern.

The labels that do not currently require neutralization of monochloramine (chloramine) must be amended to make neutralization mandatory (see Section V). The Agency believes neutralization is already a common industry practice, therefore, the required label amendments will ensure that all registered labels are consistent with current processes.

If used as directed and neutralization is conducted, exposure of terrestrial receptors is not expected from the registered uses. Therefore, no terrestrial environmental fate data are required to estimate potential exposure of non-target organisms. In addition, the Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for ammonia and ammonium sulfate.

2. Ecological Effects Assessment

An ecological effects risk assessment was not conducted for this chemical because of a lack of exposure to non-target organisms.

The Agency believes that ecological risks from the use of ammonia and ammonium sulfate are expected to be minimal based on the environmental fate of these chemicals once neutralized, which suggests negligible exposure to the environment.

3. Ecological Incidents

No ammonia and ammonium sulfate incidents have been reported in the Office of Pesticide Programs (OPP) Incident Data System (IDS) for the period spanning 2000 to September 13, 2017.

4. Ecological and Environmental Fate Data Needs

The Agency does not anticipate any further ecological and environmental fate data needs for the ammonia and ammonium sulfate registration review.

C. Endangered Species Assessment

The Agency has no expectation for the registered pesticide uses of ammonia and ammonium sulfate to cause direct or indirect adverse effects to threatened and endangered species. Due to label restrictions mandating the neutralization of effluent water until chloramine is no longer detected, environmental exposure is unlikely. No adverse modification of any designated critical habitat for such species is expected from the use of ammonia and ammonium sulfate. The Agency is making a "no effect" determination for ammonia and ammonium sulfate under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required.

D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the Agency reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the Agency evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent risk assessment for ammonia and ammonium sulfate, the Agency reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by

FFDCA Section 408(p), ammonia and ammonium sulfate are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The Agency has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife, similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the Agency will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA Section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, the Agency issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[5] and includes some pesticides scheduled for registration review and chemicals found in water. Neither ammonia or ammonium sulfate are currently scheduled for screening. However, it should be noted that ammonia and ammonium sulfate will be screened for their potential to interact with the endocrine system. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[6]

In this interim decision, the Agency is making no human health or environmental safety findings associated with the EDSP screening of ammonia and ammonium sulfate. Before completing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination.

IV. Interim Registration Review Decision

A. Risk Mitigation and Regulatory Rationale

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this Interim Registration Review Decision for ammonia and ammonium sulfate. The Agency's Interim Decision is (1) that no additional data are needed for the active ingredients, and (2) changes to the affected labels are needed at this time (see Appendix A). In addition, the Agency does not expect ammonia and ammonium sulfate to have direct or indirect adverse effects to non-listed and listed species or to adversely modify any designated critical habitat for such species and has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species. EPA determined that no pollinator exposure and

[5] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[6] http://www.epa.gov/endo/

effects data are necessary to make a final registration review decision for ammonia and ammonium sulfate. This Interim Decision does not cover the EDSP component of this registration review case and is being issued pending its evaluation.

V. Next Steps and Timeline

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the Interim Registration Review Decision for Ammonia and Ammonium Sulfate. A Federal Register Notice will announce the availability of this Interim Decision. EPA determined that no pollinator exposure and effects data are necessary to make a final registration review decision for ammonia and ammonium sulfate. A final decision on ammonia and ammonium sulfate registration review cases will occur after the EDSP FFDCA section 408(p) determination.

Label amendments for products formulated with ammonia and ammonium sulfate are required as discussed herein and set forth in Appendix A.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is published in the docket, ammonia and ammonium sulfate registrants will be required to submit amended labels that include the label changes described in Appendix A. The amended labels will be required to be submitted to the Agency for review within 60 days following publication of the Interim Registration Review Decision.

VI. Appendix

Appendix A: Required Labeling Changes for Ammonia and Ammonium Sulfate

Description	Amended Label Language for End-Use Products	Placement on Label
Addition of required neutralization of effluent water containing monochloramine (chloramine). EPA Registration Numbers: • 1448-432 • 1448-433 • 1448-442 • 1706-240 • 9386-49 • 74655-39	"If monochloramine (chloramine) is detected in the effluent, it must be neutralized by the addition of sodium meta-bisulfite until the monochloramine (chloramine) is no longer detected."	Directions for Use
Revise the active ingredient to list correct active ingredient. EPA Registration Numbers: • 1448-432 • 1448-433 • 1448-442 • 9386-49	Change ammonia to ammonium sulfate.	Ingredient Statement